

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 13 DEC 2004

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Applicant's or agent's file reference 421/80 PCT	FOR FURTHER ACTION See Form PCT/IPEA/416																									
International application No. PCT/US04/07304	International filing date (day/month/year) 11 March 2004 (11.03.2004)	Priority date (day/month/year) 12 March 2003 (12.03.2003)																								
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00 and US Cl.: 514/12																										
Applicant UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>    </u> sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u>                    </u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 17 September 2004 (17.09.2004)	Date of completion of this report 09 November 2004 (09.11.2004)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Kevin E. Weddington <i>J. Roberts for</i> Telephone No. (571) 272-1600																									

Form PCT/IPEA/409 (cover sheet)(January 2004)

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/07304

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

☒ the international application as originally filed/furnished

☒ the description:

pages 1-27 as originally filed/furnished

pages\* NONE received by this Authority on \_\_\_\_\_

pages\* NONE received by this Authority on \_\_\_\_\_

☒ the claims:

pages 28-30 as originally filed/furnished

pages\* NONE as amended (together with any statement) under Article 19

pages\* NONE received by this Authority on \_\_\_\_\_

pages\* NONE received by this Authority on \_\_\_\_\_

☒ the drawings:

pages NONE as originally filed/furnished

pages\* NONE received by this Authority on \_\_\_\_\_

pages\* NONE received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/figs NONE

☒ the sequence listing (specify): NONE

☒ any table(s) related to the sequence listing (specify): NONE

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/figs NONE

☒ the sequence listing (specify): NONE

☒ any table(s) related to the sequence listing (specify): NONE

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/07304

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims <u>1-35</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-35</u>	NO
Industrial Applicability (IA)	Claims <u>1-35</u>	YES
	Claims <u>NONE</u>	NO

### 2. Citations and Explanations (Rule 70.7)

Claims 1-35 meet the criteria set out in PCT Article 33(2) as having novelty in the pharmaceutical art.

Claims 1-35 meet the criteria set out in PCT Article 33(4) as having industrial applicability in the pharmaceutical art.

Claims 1-35 lack an inventive step under PCT Article 33(3) as being obvious over Beck et al. (6,197,746 B1).

Beck et al. teach the use of secretin and secretin compounds to treat autism and other neurological, behavioral and immunological disorders.

The instant invention differs from the cited reference in that the cited reference does not teach secretin is used to treat schizophrenia and schizoaffective disorder. However, one skilled in the art would have been motivated to administer the said secretin to a subject suffering from schizophrenia since schizophrenia is a behavioral disorder and secretin is known to treat behavioral disorders. Thus to treat schizophrenia with secretin is expected in the absence of evidence to the contrary.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/07304

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61K 38/00

US CL : 514/12

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CAS-ONLINE, EAST**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,197,746 B1 (BECK et al.) 06 March 2001 (06.03.2001), see the entire document.	1-35

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

25 July 2004 (25.07.2004)

Date of mailing of the international search report

13 AUG 2004

Name and mailing address of the ISA/US

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